

PTO/SB/08b (07-09)

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

13

		<b>Complete if Known</b>	
Application Number		10,575,049	
Filing Date		April 5, 2006	
First Named Inventor		David De Kretser	
Art Unit		1644	
Examiner Name		Maher M. Haddad	

Attorney Docket Number PARA003US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	67	SUGIYAMA M., et al., "Expression of activin A is increased in cirrhotic and fibrotic rat livers," <i>Gastroenterology</i> , 114(3):550-558 (1998)	
	68	TAKABE K., et al., "Recombinant adenovirus vector encoding follistatin: A potential tool to stimulate liver regeneration," AASLD Abstract No. 351 from <i>Hepatology</i> , October 1999	
	69	THOMAS T., et al., "Inhibins, activins, and follistatins: Expression of mRNAs and cellular localization in tissues from men with benign prostatic hyperplasia," <i>The Prostate</i> , 34(1): 34-43 (1998)	
	70	"Ulcerative Colitis," From National Institute of Diabetes and Digestive and Kidney Diseases (NIH Publication No. 95-1597, April 1992)	
	71	WANG E., et al., "Identification of naturally occurring follistatin complexes in human biological fluids," <i>Bioi. Reprod.</i> , 60:8-13 (1999)	
	72	WEBSITE: "Facts about pulmonary fibrosis and interstitial lung disease," American Lung Association website, originally www.lungusa.org/diseases/pulmfibrosis on 7 November 2000 - enclosed version downloaded from http://209.208.158.222/diseases/pulmfibrosis.html on 1 July 2004	
	73	WEBSITE: NADEL, M., "Crohn's Disease (Granulomatous Ileitis and Colitis)", Internet site: http://155.37.5.42/TMGEN/67062160.htm on 6 December 2000 (enclosed copy downloaded on 25 June 2004)	
	74	YASUDA H., et al., "Activin A: An autocrine inhibitor of initiation of DNA synthesis in rat hepatocytes," <i>J. Clin. Invest.</i> , 92(3):491-1496 (1993)	
	75	YASUDA H., et al., "Antifibrogenic effect of a deletion variant of hepatocyte growth factor on liver fibrosis in rats," <i>Hepatology</i> , 24(3): 636-642 (1996)	
	76	YUEN M.F., et al., "Transforming growth factor-β 1, activin and follistatin in patients with hepatocellular carcinoma and patients with alcoholic cirrhosis," <i>Scand. J. Gastroenterol.</i> , 37(2):233-238 (2002)	

Examiner Signature		Date Considered	
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				Examiner Name	Maher M. Haddad
Sheet	10	of	13	Attorney Docket Number	PARA003US

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	77	ZHU J, et al., "Rapamycin inhibits hepatic stellate cell proliferation in vitro and limits fibrogenesis in an <i>in vivo</i> model of liver fibrosis," <i>Gastroenterology</i> , 117(5):1198-1204 (1999)	
	78	AZUMA T, et al., <i>Hepatology</i> , 34(4-2):395A (2001) (abstract)	
	79	MURATA T, et al., "Anti-activin A antibody (IgY) specifically neutralizes various activin A activities,: <i>Proc. Soc. For Exp. Biol. and Med.</i> , 211(1):100-07 (1996)	
	81	DE KRETSER DM, et al., "Activin A and Follistatin: Their role in the acute phase reaction and inflammation," <i>J. of Endocrinology</i> , 161(1):195-98 (1999)	
	82	VAN EYLL J, et al., "Shh-dependent differentiation of intestinal tissue from embryonic pancreas by Activin A," <i>J. of Cell Science</i> , 117(10):2077-86	
	83	HEDGER M, et al., "The regulation and functions of activin and follistatin in inflammation and immunity," <i>Vitam Horm</i> , 85:255-97 (2011)	
	84	LIN S-Y, et al., "Regulation of Ovarian Function by the TGF-β Superfamily and Follistatin," <i>Reproduction</i> , 126:133-48 (2003)	
	85	AMTHOR H, et al., "Follistatin Regulates Bone Morphogenetic Protein-7 (BMP-8) Activity to Stimulate Embryonic Muscle Growth," <i>Developmental Biology</i> , 243:115-27 (2002)	
	86	ZHANG Y-Q, et al., "Regulation of the Expression of Follistatin in Rat Hepatocytes," <i>Biochimica et Biophysica Acta</i> , 1354:204-10 (1997)	
	87	GAMER L, et al., "GDF11 is a Negative Regulator of Chondrogenesis and Myogenesis in the Developing Chick Limb," <i>Developmental Biology</i> , 229:407-20 (2001)	

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	88	PATEL K, et al., "Molecules in Focus: Follistatin," <i>The International J. of Biochemistry and Cell Biology</i> , 30:1087-93 (1998)	
	89	IEMURA S-I, et al., "Direct Binding of Follistatin to a Complex of Bone-Morphogenetic Protein and its Receptor Inhibits Ventral and Epidermal Cell Fates in Early Xenopus Embryo," <i>PNAS USA</i> , 95:9337-42 (1998)	
	90	WANKELL M, et al., "Impaired Wound Healing in Transgenic Mice Overexpressing the Activin Antagonist Follistatin in the Epidermis," <i>The EMBO Journal</i> , 20:5361-72 (2001)	
	91	USSN 10/755,545 First Office Action pages 1-15, 2007	
	92	USSN 10/755,545 Second Office Action Pages 1-17, 2008	
	93	USSN 10/755,545 Third Office Action Pages 1-26, 2008	
	94	USSN 12/399,610 First Office Action Pages 1-14, 2010	
	95	ALCOLADO R., et al., "Pathogenesis of liver fibrosis," <i>Clin. Sci. (Lond)</i> , 92(2):103-112 (1997)	
	96	GRECO B., et al., "Atherosclerotic Ischemic Renal Disease," <i>Amer. J. Kidney Diseases</i> , 9(2):167-187 (1997)	
	97	ICHIKAWA T., et al., "Transforming growth factor $\beta$ and activin tonically inhibit DNA synthesis in the rat liver," <i>Hepatology</i> , 34(5): 918-925 (2001)	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10,575,049
		Filing Date	April 5, 2006
		First Named Inventor	David De Kretser
		Art Unit	1644
		Examiner Name	Maher M. Haddad
(Use as many sheets as necessary)			
Sheet	12	of	13
		Attorney Docket Number	
		PARA003US	

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Examiner Signature	/Maher Haddad/	Date Considered	09/15/2011
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